

# **EXHIBIT 14**

**C · T · F · A**  
*Representing the personal care products industry*

F 14  
*E. Edward Kavanaugh*  
*President*

**DRAFT MINUTES**

**TALC INTERESTED PARTY TASK FORCE**

CTFA  
Main Conference Room  
1101 17th Street, N.W., Suite 300  
Washington, DC 20036

Plaintiff's Exhibit  
No.  
**P-14**

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July 21, 1993

A meeting of the Talc Interested Party Task Force was held at CTFA on Wednesday, July 21, 1993 beginning at 10:00 a.m. Those in attendance were:

Dr. Laureen MacEachern - COLGATE-PALMOLIVE  
Ms. Kate Trammell - MAYBELLINE  
Mr. William Ashton - JOHNSON & JOHNSON (Guest)  
Mr. Mike Chudkowski - JOHNSON & JOHNSON  
Mr. Richard Zazenski - LUZENAC AMERICA  
Dr. Martin Roddy - NOXELL  
Ms. Marjorie McTernan - JOHNSON & JOHNSON (Guest)  
Dr. Stephen Gettings - CTFA (Liaison)

**I. OPENING REMARKS**

1. SGettings opened the meeting and apologized for calling it at such short notice. He noted that the purpose of the meeting was to discuss the outcome of a meeting SGettings held with members of the Planning Committee of the International Society of Regulatory Toxicology & Pharmacology (IS RTP), held at the ToxForum meeting on July 14th, 1993. The minutes of the last meeting were approved with no changes.

**II. INFORMATION EXCHANGE/GENERAL DISCUSSION**

1. SGettings noted that ISTRP have been asked by FDA to organize a 1-2 day symposium on talc safety and related issues (93-TA-10). The Task Force was alerted as to this possibility in February, 1993 (93-TA-07).
2. At the IS RTP Planning Committee meeting SGettings was

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apprised of the following:

The intended target audience are regulatory specialists, toxicologists, food/drug/cosmetic/medical device manufacturers, academicians and medical professionals. At least 100 attendees are anticipated.

From the meeting, FDA hope to gain insight into the relevance of recent toxicological and epidemiological studies to the safety of regulated products. FDA would like participants to address not only the validity of experimental approach but also risk "under conditions of use." FDA does not anticipate that they will be able to develop a regulatory decision from this program alone.

The meeting will be held in the Washington, DC area, possibly at the NIH auditorium. It will be scheduled for late fall (probably November) or for early 1994 (January).

The symposium will relate principally to ingredient use and safety as it applies to consumer products. (FDA anticipate that scientific studies relating to occupational uses of talc will contribute to the program as it relates to consumer products). Relative to OTC drug use of talc, FDA feel that someone from USP should at least serve on the panel for discussion and possibly make a presentation on USP specifications. Apparently, the OTC group thinks there should be a discussion of product labeling as it applies to OTC products, i.e., diaper rash could be discussed for adequacy and possible suggestions. FDA feel that this portion of the program would be useful in assessing whether or not the current USP specifications are adequate.

The proceedings of the symposium will probably be published (probably as a meeting summary, by rapporteurs).

FDA is budgeting \$10,000 as financial contribution to the effort; industry has been asked to contribute \$20,000; the remainder will be provided by IS RTP.

The anticipated format is to have some sort of "expert panel" in attendance throughout the meeting. FDA suggest that someone from industry (possibly a member of the CIR Expert Panel) and a consumer representative be invited to sit on the panel. Following the presentations, FDA would like to have ample time for discussions from the floor. The discussion will be led by members of the panel.

3. The following agenda has been proposed following discussions between IS RTP and FDA:

**DAY 1** - The first day of the symposium will concentrate on inhalation health considerations, and will take the following format:

Introduction - introduce the topic, present the reasons for holding the symposium and provide some background about studies conducted on the safety of talc (historical perspective). IS RTP have been asked to identify someone who can serve in this capacity.

Manufacture of talc - To discuss (1) how, and where, it is obtained (mineral sources), (2) specifications for talc as used in different products, and (3) quality control including steps to control and monitor asbestos contamination. FDA stress that it is important for this presentation to describe the "specifications" for the material that is actually used in different products (i.e., particle size, impurities, etc). CTFA has been asked to identify a suitable speaker.

Uses of talc in different FDA-regulated products - Specifically, what are the requirements for the use of talc in foods, drugs, cosmetics and medical devices and why they are critical. (FDA suggest that this presentation may be combined with the previous one).

Regulatory status of talc in the different product categories - This topic will be discussed by one (or more) FDA officials.

Health Perspectives - Presentation and critique of the NTP inhalation study by various presenters (eg., Oberdorster, Goodman etc).

Panel/Floor discussion

**DAY 2** - The second day will primarily cover ovarian cancer and talc, but epidemiology as it relates to inhalation exposure will also be discussed.

Introduction - historical overview of the various epidemiology studies on talc (possibly in 2 parts):

- a. Epidemiology studies of occupational exposures (inhalation).
- b. Epidemiology studies on ovarian cancer.

Risk factors in ovarian cancer

Harlow's Epidemiology studies of ovarian cancer and perineal exposure.

Meta-Analysis - Discussion of the pros and cons of meta-analysis as a general statistical tool in measuring correlations in epidemiology studies.

Panel/Floor discussion

Moderator wrap-up and close

**III. ACTION/NEXT STEPS**

1. The Task Force agreed that it was clear that the ISTRP meeting will be held irrespective of industry input, but that such input was important. The Task Force agreed that it was important that, as industry's representative, SGetttings continue to participate at the ISRTP Planning Committee meetings and to offer advice and suggestions as outlined by the Task Force.
2. The Task Force agreed that the level of sponsorship requested by industry was not prohibitive. CTFA will send out commitment forms requesting total sponsorship from the Task Force of \$20,000 (depending upon the number of participants, as low as \$1,000 per company).
3. The Task Force agreed that Dr. Bruce Semple (formerly of J&J, now with P&G) should be approached and asked to represent industry on the Panel (both days of the meeting).
4. The Task Force agreed that a representative of one of the talc suppliers should make a presentation on (1) the production, processing and quality control of talc manufacturer; and (2) particle size and specifications for different product applications. RZazenski agreed to provide a presentation outline and a suggested speaker within the next few days. The Task Force agreed that all speakers will be representing the industry and that the Task Force will approve the contact of each industry presentation.
5. The Task Force agreed that a representative of a finished-product manufacturers should make a presentation on consumer use/risk assessment of cosmetic products containing talc. SGetttings will get clarification on whether other speakers will address similar issues as they relate to other talc uses. The Task Force suggested that BSemple would again be the most appropriate industry representative. The Task Force agreed to begin assembling data which might form the basis of such a presentation. It was noted that some of this information (on particle size and product notices) had previously been requested by FDA and that the Task Force had not been successful in collecting such information. WAshton

agreed to review, in particular, J&J's published data on exposure to talc. RZazenski noted that a lot of useful information could be derived from the report prepared by JKalse for the Task Force. LMacEachern noted the presentation should reference recent studies on talc (93-TA-12). LMacEachern noted that the presentation should emphasize the safety of talc use.

6. The Task Force agreed to review available information on occupational exposure from inhalation, and to discuss this issue at a follow-up meeting.
7. The Task Force agreed that both Dr. Oberdorster and Dr. Wehner (both co-authors of the BEC Report) should be proposed as speakers (on lung overload mechanisms and the biological implausibility of ovarian cancer from talc exposure, respectively). The Task Force agreed that industry should arrange for their attendance (at cost), even if they are not selected as speakers. It was also suggested that the Task Force may wish to arrange for the attendance of other consultants if necessary.

#### IV. ADJOURNMENT/NEXT MEETING

1. It was noted that SGettins next meets with ISRTP in early August. The Task Force agreed to hold a follow-up conference call within the next few days and to arrange a Task Force meeting in early September.
2. There being no further business, the meeting was adjourned.

Respectfully submitted,

*Formulate Questions/answers regarding  
anything on talc*

Stephen D. Gettins, Ph.D., D.A.B.T.  
CTFA

*TArc - inadequate evidence to show  
carcinogenicity*

*— literature survey in publications —*

*ISRP - Industry FRIENDLY*

*Exposure data into presentation - Consumer use*

*Spots question from panel or audience, need experts to address questions.  
Larger TArc comm., Brooklyn Coll.*

*— 2 wks for search*

*— Press release tomorrow —*

*— Mach Rose (Geological Survey)*

*Silica - issue cosmetic talc (B.P.)  
that contain crystalline silica that  
(0.1%) that is a carcinogen,*

*Industrial use - labeling req'd if > 0.1% silica*

# EXHIBIT 15

FEB 13 '98 02:37PM CTFA1

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C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

## MEMORANDUM

**DATE:** February 13, 1998

**E. EDWARD KAVANAUGH**  
P R E S I D E N T

**TO:** **TALC INTERESTED PARTY TASK FORCE**  
**FROM:** Pandora Dennis  
Administrative Assistant - Science

Please deliver this and the following page(s) to the corresponding individual in your company.  
Thank you.

Ms. Debra Ambrose/POLAR MINERALS/(812) 838-4744  
Mr. William Ashton/JOHNSON & JOHNSON/(908) 874-1254  
Ms. Donna Beach/COSMAIR/(908) 499-2929  
Dr. Daniel Briggs/PROCTER & GAMBLE/(513) 626-4399  
Mr. Michael Chudkowski/JOHNSON & JOHNSON/(908) 874-1254  
Mr. Shawn Hays/POLAR MINERALS/(404) 934-4376  
Dr. John Hopkins/JOHNSON & JOHNSON/(908) 874-1155  
Mr. Daniel Johnson/COMBE INCORPORATED/(914) 694-1585  
Mr. John Kelse/RT VANDERBILT COMPANY/(203) 853-1452  
Mr. Louis Kotyuk/WHITTAKER, CLARK & DANIELS/(800) 833-8139  
Mr. Mike Larson/MINERALS TECHNOLOGIES/(212) 878-1804  
Dr. Laurie Pan/MARY KAY COSMETICS/(214) 905-6799  
Dr. Steve Pennisi/COMBE INCORPORATED/(914) 694-1585  
Mr. Thomas Pallone/ALBERTO-CULVER/(708) 450-3067  
Dr. Thomas Re/BRISTOL-MYERS/(908) 851-6250  
Ms. Janice Rogers/GILLETTE/(301) 590-1535  
Dr. Bruce Semple/PROCTER & GAMBLE/ (513) 626-2977  
Dr. Tracey Spriggs/COLGATE-PALMOLIVE/ (908) 878-7844  
Ms. Elaine Stern/HELENE CURTIS/(312) 384-3539  
Ms. Joan Thomas/CTPA/(011) 441714938061  
Dr. Maureen Toulon/AVON/(914) 369-2898  
Mr. Richard Zazenski/LUZENAC AMERICA/(303) 643-0446

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# **EXHIBIT 16**



## Regulatory Issue

### National Toxicology Program (NTP)

- Coordinates Interagency Toxicological Testing
- Publishes Report on Carcinogens (RoC)
- Minimal Threshold for Carcinogenic Listing
- Listing Triggers OSHA and Prop 65 Labeling
- Conducted Talc Inhalation Study on Rodents
- Nominated Talc for Review in 2000

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## Talc Health Issues

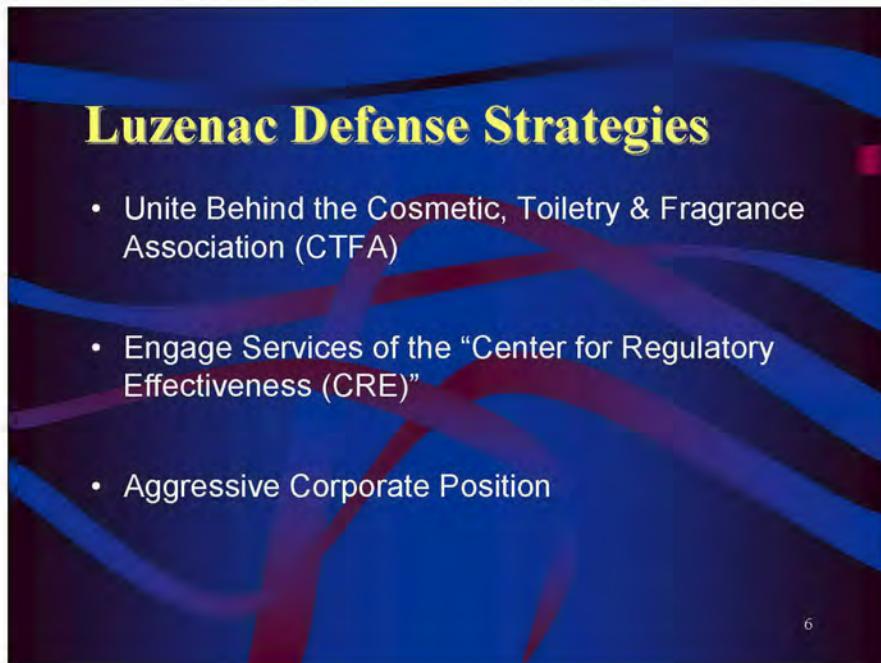
- Risk Factor in Ovarian Cancer
  - Perineal dusting by women
  - No causal explanation
- 1992 NTP Rodent Study
  - Lung tumors in female rats
  - Lung overload phenomenon
- Association with Asbestos
  - Long-held public perception
  - Chemical similarity

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## OUTLOOK

- Deferral Due to “Fatal Flaws” in Draft Report
- Temporary “Reprieve” for 2-3 Years
- Insist Upon the Need for Additional Studies
- Updates on Gertig et al. Study of 76,630 U.S. Women - No Increased Risk with Talc Usage
- Re-examine Prior Epidemiology Studies - Negative Dose Response?
- IARC Re-examination of Talc a Possibility

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# **EXHIBIT 17**



92-SE-328

92-SAC-24

*E. Edward Kavanaugh*  
President

## MEMORANDUM

**TO:** Scientific Advisory Committee  
**FROM:** G.N. McEwen, Jr., Ph.D., J.D.  
Vice President - Science  
**DATE:** July 17, 1992  
**SUBJ:** TALC SAFETY INTERESTED PARTY

The conclusions in two recent studies question the safety of cosmetic grade talc. A draft report of one study, involving daily, lifetime inhalation of massive amounts of talc in rats and mice, concludes there is clear evidence that talc is a carcinogen for female rats, and some evidence that it is a carcinogen for male rats. There was no evidence of carcinogenicity in male or female mice. The other study concludes that there is an association between talc use in the perineal area and ovarian cancer in women. CTFA will provide copies of these reports upon request.

Although CTFA is convinced that these studies do not suggest any hazard from normal use or foreseeable misuse of personal-care products or cosmetics containing talc, such reports may have wide implications for classification and characterization of talc by various regulatory agencies, including OSHA, FDA, and California's Office of Environmental Health Hazard Assessment, responsible for listing substances for Proposition 65.

CTFA has instituted an Interested Party Task Force to address these studies. The Task Force is developing a strategy to defend the continued safe use of talc, and is open to those companies willing to provide financial support for this activity. For further information on how to join the Task Force, please contact Dr. Stephen Gettings, Director, Toxicology, CTFA.

GNM/pcl  
cc: Scientific Advisory  
Executive Committee

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# **EXHIBIT 18**

CALL REPORT  
Luzenac America

Date: 11/8/93 Regional Manager: J. A. Tracy  
Date of Call: 11/8/93 Accompanied By: \_\_\_\_\_

Cust Name: Carter Wallace Cust #: 05258/0000  
City & State: Trenton, NJ Industry Code: 05:001  
Contacts: Deborah Richardson, Purchasing Agent

Prod#: 11234 Descrip: Vertal 1500USP Qty: 200TPY Price:

Comp#1: DeGussa Prod: Hydrated silica Qty: \_\_\_\_\_ Price: \_\_\_\_\_  
Comp#2: \_\_\_\_\_ Prod: \_\_\_\_\_ Qty: \_\_\_\_\_ Price: \_\_\_\_\_

PRODUCT APPLICATION: Dusting of latex rubber condoms.

OBJECTIVE: Find out the status of the replacement of talc, and discuss the Johnson plant closing.

SUMMARY: Debbie said that they have switched from talc to hydrated silica that they get from DeGussa. Huber is another approved supplier. She said that the silica is so light and fluffy that they have built a closed dusting system to contain the dust. I asked her if they were not concerned about the use of silica. She said they were, but felt that the only problem was with respirable silica. Their closed system they feel is sufficient protection for their workers.

She said that they were pleased with the performance of talc, but were concerned because a CTFA report in July 1992 said that there was suspicion that talc could cause ovarian cancer. Although the report didn't say that it was a cause, Carter Wallace is concerned about future litigation.

Debbie said that if silica becomes a problem, they might look at talc again.

ACTION REQUIRED: No action required.

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# **EXHIBIT 19**

January 2, 2002

**Principal Argument for Adopting Luzenac America's NTP Strategy**

We engaged the council of the Center for Regulatory Effectiveness ("CRE") in November 2000 for the purpose of providing us direct assistance in developing a business strategy to challenge the NTP talc review. CRE 'knows' NTP. CRE knows many of the individuals personally – most importantly, the key decision-makers. They know how NTP operates, both technically and politically. CRE knows how NTP 'values' the significance of published human and animal studies. CRE knows the influential people from the other agencies who get involved in the review process. Simply put, CRE possesses the knowledge and experience to help us effectively mount a strategic challenge to the NTP talc review.

From the beginning, CRE has recommended that we adopt an aggressive (professional) approach with NTP. Our technical (and legal) arguments have alternated between Luzenac and CRE letterhead – designed to maximize the intended effect.

Presently, CRE believes the request for by Dr. Olden (NTP Director) presents us with an opportunity to 'proactively' submit a detailed literature research paper that not only directly addresses the unresolved issues (mineralogy), but also other controversial issues that we anticipate will (or should) resurface (epidemiology, causation, consistency of results). It affords us the opportunity to initiate the agenda for discussions with NTP.

To reject their recommendations in this important process would be unwise.

**For the Record**

In November 2000, Luzenac discovered the "fatal flaw" in the NTP report. With the help of CRE we exploited this issue with NTP which ended in the deferral decision by the NTP Executive Committee.

The public record will reflect that Luzenac America was the only talc-interested-party who recognized this fatal flaw (and winning strategy).

**Meli to NTP; Nov. 30, 2000**

"A critical error in the fundamental logic of the NTP's own line of argument categorically invalidates the NTP conclusion....proposed by RG1 and RG2 that "Talc not containing asbestos fibers is reasonably anticipated to be a human carcinogen."

'It is also recommended that the Board of Scientific Counselors Subcommittee notify Review Groups 1 & 2 that their conclusion relative to talc not containing asbestos fibers is not supported by the data. The arguments and assumptions made by the reviewers in the text of the Draft Background Document unquestionably contradict their own conclusion..."

"It is clear that the premise on which NTP has assessed the literature and safety issues relating to all forms of talc is seriously faulted and cannot be used as a reasonable basis for nomination as an anticipated human carcinogen."

**Harris to NTP; May 1, 2001**

"..and if they (RG1 and RG2 recommendations) were to be submitted to the Director of NTP and the Secretary as valid recommendations, a final decision to list talc not containing asbestos fibers in the Report would be arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law, and would be set aside by the Federal courts pursuant to the Administrative Procedure Act."



**KEY POINTS**

1. Joachim Roeser must understand that it was the strategy and actions of Luzenac America (not Luzenac Group or Eurotalc) that led to the talc deferral decision (in order for him to respect our current recommendations). Inexplicably, despite the soundness of our strategy, Luzenac Group repeatedly opposed our intended actions throughout the process.
2. CTFA and the talc interested parties have been minimally effective during this NTP review. It is a management problem. They have not demonstrated the leadership necessary to coordinate a diligent, on-going defense of talc. In the spirit of "Either lead, follow, or get out of the way", I recommend Luzenac America (with "CRE") advance our agenda with an invitation to others to follow. I do not favor the "committee approach" to NTP where no one is formally in charge.
3. I am not at all concerned about angering CTFA or any of its members who might be customers. With our entire business literally at stake, we have the "standing" to do what we feel is necessary in this battle for survival. As an aside, only J&J and possibly one other company expressed interest in further funding of the consultants utilized by CTFA last December.
4. We have every right to employ scientific reasoning and logic to the evaluation of health studies involving talc (outside of mineralogy issues). If we bring to light questionable conclusions or flaws in a published study, other experts can then be asked to forward their opinions on the issues. At a minimum, the NTP reviewers would be obligated to discuss and debate our points of contention (e.g., talc detected in ovarian tissue).

# **EXHIBIT 20**

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July 12, 2006

Judy Brown

7/18/2006 10:54:00 AM

Mark Ellis  
President  
Industrial Minerals Association – North America  
Suite 301  
2011 Pennsylvania Ave. N.W.  
Washington, D.C. 20006

Dear Mr. Ellis:

For the benefit of “talc interested parties” in IMA-NA and IMA-Europe, I would like to summarize a few key points as to the reasoning behind Luzenac’s decision to forego any further funding of the University of Vermont talc study (re: “Mossman” study) at this time.

1. This study proposal was first brought to Luzenac’s attention in early 2005 primarily due to the diligent efforts of Bob Glenn. Luzenac has engaged the consulting services of Bob (through Crowell & Moring) for several years now. Luzenac was prepared to proceed with the study primarily because there was an excellent chance that the study could be completed and a paper written that could be made available for the IARC review in February 2006. We felt that the injection of new data into the talc/ovarian cancer debate was essential. As the months passed and other “talc interested parties” became part of the sponsorship base, numerous and frustrating delays resulted in the postponement of the start of this research project. It became evident in late 2005 that we squandered away the window of opportunity to have this study completed in time for the IARC review meeting passed

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. When IARC concluded their review and classified “perineal use of talc-based powders” as a Group 2b carcinogen, we began to question the value of proceeding any further with the Mossman study. To put it in the vernacular, the “horse has already left the barn.” Due to the considerable costs involved and deadlines no longer a factor, Luzenac (Rio Tinto Minerals) made the business decision that the potential value of this study was greatly diminished and did not warrant any further pursuit at this time.

2. The cosmetic and pharmaceutical companies engaged in the business of marketing dusting and body powders to the public have shown no enthusiasm for sponsoring new research on this issue.

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One of their primary arguments is that there are simply too many positive epidemiology studies published to stem the tide of negative sentiment

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additional expenditures for new research in this field if the cosmetic and pharmaceutical companies engaged in this business are reluctant to do so.

3. Over the last nine months Luzenac has been transformed into a new company, Rio Tinto Minerals. As a result, we are undergoing major changes in our product portfolios and business strategies. Our limited R&D resources will be applied to those products which are essential to our stability and growth. Supplying talc for the body powder market is a rather insignificant element in our overall product portfolio and does not warrant any further sponsorship for research projects to support the business.

Sincerely,

Eric Turner

Sincerely,

Eric Turner

**Employee Name**

Employee Title Line One  
Employee Title Line Two